

Australian Hospital Care (The Avenue) Pty Ltd trading as

The Avenue Hospital

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22 July 2015

Prof Jane Fisher
Jean Hailes Research Unit
Level 6 99 Commercial Road
Melbourne Vic 3004

Dear Jane,

HREC Reference number: Trial 188

Project title: Is CB-ART a useful resource for women admitted to Masada Private Hospital MBU? Assessing feasibility, acceptability and usefulness in a pilot study.

Thank you for submitting the above research project for single ethical review. This project was considered by The Avenue Hospital Ethics Committee at its meeting held on 23rd June 2015.

I am pleased to advise you that the Committee has granted ethical approval of this research project.

The nominated participating site in this project is - **Masada Private Hospital Mother Baby Unit**

The approved documents include:

Document	Version	Date
• NEAF_Form Fisher et al	FINAL	29.5.15
• Victorian Specific Module-v03 Fisher et al May 2015	Three	29.5.15
• CB-ART. PICF Interventional for Self 29th May 2015	Master	27.5.15
• CB_ART Masada Flyer	One	19.5.15
• CB-ART Baseline questionnaire	One	19.5.15
• CB-ART Follow-up telephone questionair	One	29.5.15

Approval of this project is valid from 9 July 2015 to 30July 2016 subject to the following conditions being met:

- The Coordinating Principal Investigator will immediately report anything that might warrant review of ethical approval of the project.
- The Coordinating Principal Investigator will notify the The Avenue Hospital HREC of any event that requires a modification to the protocol or other project documents and submit any required amendments in accordance with the instructions provided by the HREC. These instructions can be found at <http://www.theavenuehospital.com.au/Our-Doctors/ethics-committee.aspx>

- The Coordinating Principal Investigator will submit any necessary reports related to the safety of research participants in accordance with The Avenue Hospital HREC policy and procedures. These instructions can be found at <http://www.theavenuehospital.com.au/Our-Doctors/ethics-committee.aspx>
- The Coordinating Principal Investigator will report to the The Avenue Hospital HREC annually in the specified format and notify the HREC when the project is completed.
- The Coordinating Principal Investigator will notify the The Avenue Hospital HREC if the project is discontinued before the expected completion date, with reasons provided.
- The Coordinating Principal Investigator will notify the The Avenue Hospital HREC of any plan to extend the duration of the project past the approval period listed above and will submit any associated required documentation. Instructions for obtaining an extension of approval can be found at <http://www.theavenuehospital.com.au/Our-Doctors/ethics-committee.aspx>
- The Coordinating Principal Investigator will notify the The Avenue Hospital HREC of his or her inability to continue as Coordinating Principal Investigator including the name of and contact information for a replacement.

The Committee wishes you well with the research and looks forward to your first report. A reminder will be sent prior to the due date.

Should you require any further information or clarification please contact me at any time – GogerlyB@ramsayhealth.com.au.

Yours sincerely



Barbara Gogerly
HREC Coordinator

For
AP Wendy Brown, Chair
The Avenue Hospital HREC

This HREC is constituted and operates in accordance with the National Health and Medical Research Council's (NHMRC) *National Statement on Ethical Conduct in Human Research (2007)*. The processes used by this HREC to review multi-centre research proposals have been certified by the National Health and Medical Research Council.